

In the Claims

Claims 1-46 (Canceled)

47. (New) A foam or film device for topical delivery of a therapeutically effective agent to a vaginal, nasal, buccal, scrotal or labial epithelium,

wherein said device is prepared from a composition comprising at least one substrate polymer selected for the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, gelatin, alginic acid, alginic acid sodium salt, polyethylene glycol, pectin, collagen, poloxamer, carbopol, polycarbophil acid crosslinked by di-vinyl glycol, polyacrylic acid crosslinked by di-vinyl glycol, microcrystalline cellulose, polyacrylic acid, polyethylene glycol, polypropylene glycol, divinyl glycol, polypropylene oxide, carboxymethyl cellulose, hydroxyethyl cellulose, polylactide, polyglycolide, polymethacrylic acid, poly- γ -benzyl-L-glutamate, polypropylene fumarate, poly- ϵ -caprolactone, poly-butylene terephthalate, polyvinyl alcohol, polyvinyl ether, poly-1-vinyl-2-pyrrolidinone, 2,5-dimethyl-1,5-hexadiene, divinyl benzene, polystyrene-divinyl benzene, poly-bis(*p*-carboxy-phenoxypropane)-co-sebacic acid, poly- β -hydroxybutyrate, poly- β -butyrolactone, tetraethylorthosilicate and dimethyldiethoxysilane, each alone or in admixture; and

a therapeutically effective agent;

wherein said foam or film device is preformed into a solid or semi-solid foam tampon, foam tablet, foam cylinder, foam or film strip, foam or film pad, foam or film pillow, foam or film tube, foam or film sheet, foam or film sphere, foam or film ring, foam bead or a single or double sided foam or film sheet, or is a liquid preparation that forms a foam or film layer device upon contact with an epithelial tissue or with a surface of non-foam or non-film device made of different material.

48. (New) The device of claim 47 wherein said therapeutically effective agent is selected from the group consisting of a non-steroidal anti-inflammatory agent, anti-osteoporosis agent, calcium channel antagonist agent, local anesthetic agent, potassium channel antagonist agent, β -adrenergic agonist agent, vasodilatory agent, cyclooxygenase inhibitor agent, anti-fungal agent, antiviral agent, antimicrobial agent, antiparasitic agent, anti-epileptic agent, anti-migraine agent, anti-HIV agent, anti-neurodegenerative agent, chemotherapeutic agent, anti-neoplastic agent and opioid analgesic agent.

49. (New) The device of claim 48 wherein said nonsteroidal anti-inflammatory agent is selected from the group consisting of ketorolac, aspirin, ibuprofen, indometacin, phenylbutazone, bromfenac, fenamate, sulindac, nabumetone and naproxen;

wherein said calcium channel antagonist agent is selected from the group consisting of diltiazem, isradipine, nimodipine, felodipine, verapamil, nifedipine, nicardipine and bepridil;

wherein said potassium channel blocker agent is selected from the group consisting of dofetilide, almokalant, sematilide, ambasilide, azimilide, tedisamil, sotalol, piroxicam and ibutilide;

wherein said β -adrenergic agonist agent is selected from the group consisting of terbutaline, salbutamol, metaproterenol, ritodrine;

wherein said COX-2 or COX-1 inhibitor agent is selected from the group consisting of naproxen, ketoprofen, ketorolac, indomethacin, diclofenac, teroxicam, celecoxib, meloxicam and flosulide;

wherein said vasodilator agent is selected from the group consisting of nitroglycerin, isosorbide dinitrate, and isosorbide mononitrate;

wherein said bisphosphonate agent is selected from the group consisting of alendronate, clodronate, etidronate, pamidronate, tiludronate, ibandronate, zoledronate, alpadronate, residronate and

polyethylene oxide, hydropropyl methylcellulose, gelatin, alginic acid, alginic acid sodium salt, polyethylene glycol, pectin, collagen, poloxamer, carbopol, microcrystalline cellulose, polycarbophil acid crosslinked by di-vinyl glycol or polyacrylic acid crosslinked by di-vinyl glycol, each alone or in admixture.

52. (New) The device of claim 51 wherein said composition further comprises a penetration enhancer, sorption promoter, mucoadhesive agent, hydrophilic or hydrophobic release modifier, each alone or in admixture.

53. (New) The device of claim 52, wherein said penetration enhancer is selected from the group consisting of sodium caproate, sodium caprylate, sodium caprate, sodium laurate, sodium myristate, sodium palmitate, sodium palmitoleate, sodium oleate, sodium ricinoleate, sodium linoleate, sodium stearate, sodium lauryl sulfate, sodium tetradecyl sulfate, sodium lauryl sarcosine, sodium dioctyl sulfosuccinate, sodium cholate, sodium taurocholate, sodium glycocholate, sodium deoxycholate, sodium taurodeoxycholate, sodium glycodeoxycholate, sodium ursodeoxycholate, sodium chenodeoxycholate, sodium taurochenodeoxycholate, sodium glycol chenodeoxycholate, sodium cholylsarcosine, sodium N-methyl taurocholate, sodium tauro-24,25-dihydrofusidate, disodium polyoxyethylene-10 oleyl ether phosphate, esterification product of fatty alcohols, fatty alcohol ethoxylate with phosphoric acid or anhydride, ether carboxylate, succinylated monoglyceride, sodium stearyl fumarate, stearyl propylene glycol hydrogen succinate, mono/diacetylated tartaric acid ester of mono- and diglycerides, citric acid esters of mono- and diglycerides, glyceryl-lacto esters of fatty acids, lactic ester of fatty acids, alginate salt, ethoxylated alkyl sulfate, alkyl benzene sulfone, α -olefin sulfonate, acyl isethionate, acyl taurate, alkyl glyceryl ether sulfonate, octyl sulfosuccinate disodium, disodium undecylenamideo-MEA-sulfosuccinate, phosphatidic acid, phosphatidyl glycerol,

polyacrylic acid, hyaluronate sodium, glycyrrhetic acid, ethylene diamine tetraacetate, sodium citrate, chitosan, trimethyl chitosan, poly-L-arginine chitosan, poly-L-lysine chitosan, aminated gelatin, hexadecyl triammonium chloride, decyl trimethylammonium chloride, cetyl trimethylammonium chloride, alkyl benzyldimethylammonium chloride, diisobutyl phenoxyethoxydimethyl benzylammonium chloride, ethyl pyridinium chloride, isopropyl pyridinium chloride, N-lauryl, N,N-dimethylglycine, N-capryl, N,N-diethylglycine, polyoxyethylene coconut amine, poly-L-lysine, poly-L-arginine, lecithin, lysolecithin, hydroxylated lecithin, lysophosphatidylcholine, phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, didecanoyl-L- α -phosphatidylcholine, lauroylcarnitine, acylcarnitine, palmitoyl-D,L-carnitine, polyoxyethylene lauryl ether, polyoxyethylene monooleyl ether, ethoxydiglycol, polyoxyethylene nonylphenol polyoxyethylene octylphenol ether, polyoxyethylene cholesterol ether, polyoxyethylene soya sterol ether, α -cyclodextrin, β -cyclodextrin, γ -cyclodextrin, dimethyl- β -cyclodextrin, methylated- β -cyclodextrin, 2-hydroxypropyl- β -cyclodextrin, sorbitol, polyoxyethylene glycol ester, polyoxyethylene glycerol fatty acid ester, polyoxyethylene glycerol fatty acid ester, polyoxyethylene glyceride, polyoxyethylene vegetable or hydrogenated oil, polyoxyethylene monooleate, polyoxyethylene dilaurate, polyoxyethylene mono and dioleate, polyoxyethylene glyceryl laurate, polyoxyethylene glyceryl oleate, propylene glycol oleate, propylene glycol stearate, polyoxyethylene sorbitan monooleate, polyoxyethylene tristearate, polyoxyethylene hydrogenated castor oil, polyoxyethylene almond oil, polyoxyethylene apricot kernel oil, polyoxyethylene caprylic glyceride, polyoxyethylene capric glyceride, lauroyl macrogol glyceride;

wherein said mucoadhesive agent is selected from the group consisting of hydroxypropyl methylcellulose, carboxymethylcellulose, polylactide-coglycolide, chitosan, chitosan ester, trimethylene chloride chitosan, sodium alginate, poloxamer,

pectin, polyacrylic acid, hyaluronic acid, polyvinyl alcohol, polyvinyl pyrrolidone, polycarbophil and carbopol; and

wherein said release modifier is selected from the group consisting of polyethylene glycol 200, polyethylene glycol 8000, poloxamer, polyoxyethylene glycerylcocoate, carbopol, suppocire AS2X, suppocire CM, Witepsol H15, Witepsol W25, mineral oil, corn oil, paraffin oil, canola oil, castor oil, cottonseed oil, lecithin, peanut oil, sesame oil, soybean oil and hydrogenated vegetable oil.

54. (New) The device of claim 53 wherein said penetration enhancer is present in amount from about 0.1% to about 60%, by weight, wherein said mucoadhesive agent is present in from about 0.5% to about 10%, by weight, and wherein said release modifier is present in amount from about 5% to about 70%, by weight.

55. (New) The device of claim 54 wherein said composition further comprises a therapeutically acceptable additive or excipient, wherein said additive or excipient is a solubilizing agent, buffering agent, filler, preservative, plasticizer, surfactant or anti-oxidant.

56. (New) The film device of claim 47 comprising a single layer or multiple layers of a single or double-sided sheet.

57. (New) The device of claim 56 wherein said therapeutically effective agent is incorporated into or attached to one side or both sides of the film.

58. (New) The foam device of claim 47 wherein said therapeutically effective agent is incorporated into said foam before the foam formation or be coated on the inner pores of prefabricated foam.